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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,398	01/21/2005	Zheng Xin Dong	113P/PCT3/US	5939

7590 11/17/2008  
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EXAMINER
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GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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11/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,398	<b>Applicant(s)</b> DONG ET AL.	
	<b>Examiner</b> ANISH GUPTA	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 9-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-13 in the reply filed on 7-27-07 is acknowledged. Applicants also elected the species (Aib2, Glu3(NH-hexyl)hGhrelin(1-28)-NH<sub>2</sub>). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that Applicants have requested rejoinder of the method Groups of II, III, IV, V, VI, VII. Applicants request is acknowledged. Applicants are reminded In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder. See MPEP § 821.04(b). In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. Failure to do so may result in a loss of the right to rejoinder. However, once the product claim is deemed to be allowable, the product claims will be rejoined and will be fully examined for patentability in accordance with 37 CFR1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. See MPEP 821.04.

A search was conducted for the elected species species (Aib2, Glu3(NH-hexyl)hGhrelin(1-28)-NH<sub>2</sub>). This was found to be free of the prior art. In accordance with markush practice, the

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prior art was extended to non-elected species and prior art was found that rendered obvious the Markush group of claim 1 and species of claim 5. Claim 1-5 and 8 read on the elected species. Claims 4 and 6-7 and 9--13 are withdrawn from consideration.

2. All rejections made in the previous office action and not cited here in is hereby withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claim 1 requires that the Ghrelin analogs contain certain residues in position A2 or A3 or A4 or A5 or A6 or A7 or A8 or A9. However, dependent claims contain species that do not conform to the requirement of claim 1. For example in claim 4, the species Ac-Gly1-hGhrelin (1-5) does not conform with the requirement of claim 1. Moreover, claim 5 recites Asp3 (-O-hexyl)-hGhrelin (1-28) that does not conform to the requirements of residue A3. These are only some of the examples recited in the claims that do not properly depend on claim 1. The claims are therefore indefinite.

Claim 5 does not properly limit claim 4. Claim 5 recites Cys3(S-(CH<sub>2</sub>)<sup>9</sup>-CH<sub>3</sub>)-hGhrelin (1-28). This species does not appear in claim 4. In fact, claim 2 does not allow for such a species since AA3 is not disclosed to be cysteine.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kangawa et al (WO01/07475).

The claims are drawn hGhrelin analogs.

The reference teaches modified hGhrelin analogs. Specifically, the reference teaches Arg8-hGhrelin (1-8), that meets the limitation of claim 1 (see table 6., page 131). This meets the limitation of the claims when A1 is Gly, A2 is Ser, A3 is Ser(C(O)-R4), A4 is phe, A5 is Leu, A6 is Ser, A7 is Pro, A8 is Arg, the rest of the A variables are absent. Note that A8, Arg is one of the substitutions that is required by the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

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contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kangawa et al (US7385026).

The claims are drawn hGhrelin analogs.

The reference teaches hGhrelin of the sequence Cys3(octyl)-hGhrelin (See col. 82, lines 34). The difference between the reference and the instant application is that the reference does not specifically teach amidation of the peptide or teach decyl conjugated to the cysteine residue.

However, the reference also teaches that alkylation on the third residue results in active analogs. The reference specifically teaches that when the third residue is modified with 8 or more carbon atom containing fatty acid, Ca-releasing activity is the strongest (See col. 55, lines 15-66). Furthermore, amidation of the C-terminal end result in higher activity. For example, amidation of ghrelin (1-7) resulted in 7 times as higher activity than without amidation (see col. 75, lines 44-49). Therefore, it would have been obvious to amidate the native peptide because amidation of the C-terminal carboxylic acid enhanced activity. Furthermore, it would have been obvious to modify the Cys-hGhrelin analog with a decyl residue because anything higher than 8 carbon atoms in the third residue resulted in the strongest activity. Thus, Cys3(decyl)-hGhrelin-NH<sub>2</sub> is rendered obvious by the prior art.

As a note that claims 2-4 have been rejected since claim 5, which is dependent on claims 2-4, contains the cys containing Ghrelin analog. These claims have been rejected since it has been

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assumed that claims 2-4 required cys containing Ghrelin analog but were inadvertently omitted from the claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/  
Primary Examiner, Art Unit 1654